

matter of the invention. We have amended claims 5 and 17, and cancelled claim 24.

Claims 1, 3-5 and 11 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent Number 6,629,930 to Palma et al. (“Palma”) and US Patent Number 6,443,996 to Ting et al. (“Ting”). We have amended claims 3, 5, and 11, which depend on independent claim 1, which we have also amended.

Claims 2, 6, and 7 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Palma in view of Ting as applied to claims 1, 3-5 and 11, and further in view of US Patent Number 4,338,950 to Barlow et al. (“Barlow”).

Claim 2 depends on independent claim 1, which we have amended. We have also amended claims 6 and 7, which depend on independent claim 1.

Claims 8-10 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Palma in view of Ting, as applied to claims 1, 3-5 and 11, and further in view of US Patent Number 6,616,613 to Goodman et al. (“Goodman”). We have cancelled claims 8 and 10. We have amended claim 9, which depends on independent claim 1, which we have also amended.

Claims 12-14 and 17 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent Number 6,893,402 to Freund et al. (“Freund”) in view of Ting. We have amended claims 13, 14, and 17, which depend on independent claim 12, which we have also amended.

Claims 15 and 16 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Freund in view of Ting, as applied to claims 12-14 and 17 above, and further in view of US Patent Number 5,342,026 to Swedlow et al. (“Swedlow”). We have amended claims 15 and 16, which depend on independent claim 12, which we have also amended.

Claim 18 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Freund in view of Ting, as applied to claims 12-14 and 17 above, and in further view of Goodman. We have cancelled claim 18.

Claim 19 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Palma in view of Ting, as applied to claims 1, 3-5 and 11 and further in view of Goodman. We have amended independent claim 19.

Claims 20, 22, and 24 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Barlow in view of Ting. We have cancelled claims 20, 22, and 24.

Claim 21 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Barlow in view of Ting and in further view of US Patent Number 5,941,837 to Amano et al. (“Amano”). We have cancelled claim 21.

Claim 23 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Barlow in view of Ting, as applied to claims 20, 22, and 24, and in further view of Swedlow. We have cancelled claim 23.

### **The Amended And New Claims**

To meet the Examiner’s rejection based on 35 U.S.C. Section 112, we have amended claims 5 and 7 to replace ‘BLUETOOTH’ and ‘Zigbee’ with, respectively, ‘802.15.1’ and ‘802.15.4’. These numerical values correspond to the specific IEEE protocols associated with the trademarked names.

We have also amended independent claims 1, 12, and 19 to further specify our device for monitoring blood pressure. The device features: 1) a motion sensor (e.g., an accelerometer) that monitors a user’s motion and, in response, generates motion information; and 2) a blood pressure monitor featuring an optical system that includes a light source and detector that generate a time-dependent waveform related to the user’s heart beat. A microprocessor receives both the time-dependent waveform and the motion information. Computer code running on the microprocessor: 1) analyzes the time-dependent waveform with a mathematical model; 2) analyzes the motion information from the motion sensor to distinguish between time-dependent waveforms generated while the user is moving and at rest; and 3) calculates a blood pressure value from the time-dependent waveform generated when the user is at rest.

Support for these amendments is found throughout the specification. For example, the specification describes a blood pressure monitor featuring a light source and light detector with Fig. 2 and the associated text in paragraphs [38] – [39]. The

specification describes a microprocessor that analyzes the time-dependent waveform with a mathematical model with Fig. 4 and text in paragraphs [41] – [42]. The specification describes a microprocessor that calculates a blood pressure value from the time-dependent waveform when the user is at rest with Figs. 7, 8 and 9 and the associated text in paragraphs [32], [45], and [46].

New independent claims describe a microprocessor running computer code that calculates a blood pressure value from a derivative of the time-dependent waveform (claim 25) or by fitting the time-dependent waveform (claim 26). The specification describes both these mathematical operations in paragraph [41].

### **The Prior Art**

Palma describes a cuff-based device for measuring diastolic and systolic blood pressure, a motion-detecting sensor, a circuit for detecting and classifying movement, and a fuzzy logic controller for processing these parameters.

Ting describes a wrist-worn device for measuring blood pressure featuring a transducer-based pressure sensor.

Goodman describes a variety of blood pressure-monitoring devices, each featuring an optical sensor that measures an optical signal. A processor analyzes the optical signal along with calibration information to determine blood pressure, which is then sent wirelessly to a computer system.

Freund describes a cuff-based device for measuring blood pressure featuring an inclination sensor for measuring a position of the patient's wrist relative to their heart.

Barlow describes a portable, body-mounted device for measuring heart rate featuring a piezoelectric pressure sensor and an accelerometer to measure motion.

Swedlow describes a pulse oximeter that includes an accelerometer for measuring motion.

Amano describes a health-management device including an accelerometer for measuring motion and optical sensors for measuring pulse waves before, during, and after exercise.

## **Patentability Over The Prior Art**

The prior art fails to disclose the invention recited in our amended claims. Specifically, independent claim 1 was rejected as being obvious in view of Palma and Ting. But while Palma does describe a ‘movement classifier’, the patent focuses on a system based on a ‘constriction sleeve’ that relies on a ‘principle of operation … based on the indirect oscillometric (i.e. cuff-based) method of measurement’ (col. 3, lines 32-33; emphasis added). Ting also fails to describe an optical measurement of blood pressure, focusing instead on a pressure-measuring device that relies on a ‘sensor 10 [that] includes a transducer 12 which produces a voltage output according to pressure changes acting on its diaphragm 14’ (col. 5, lines 49-51). Because both references fail to mention optical systems, they necessarily lack any description of a ‘time-dependent waveform’ generated by an optical system, let alone a method for analyzing such a waveform using a mathematical model (as in independent claims 1, 12, 19); a mathematical derivative (as in independent claim 25); or by fitting the waveform (as in independent claim 26). Palma and Ting therefore fail to teach or suggest the basic premises of our invention.

As described in our specification, use of a motion sensor can be critical for the claimed optical measurement technique, as motion can generate artifacts in the measured waveform, thereby affecting calculation of blood pressure:

The motion sensor 17 senses acceleration, deceleration, and general motion, and sends this information to a data-processing circuit 18. Preferably, the motion sensor 17 is used to detect when a user’s hand is at rest, and is therefore in an optimal state to measure the user’s vital signs with the vital sign monitor 16. In this manner, the motion sensor 17 reduces artifacts related to movement from the vital sign measurement. (paragraph [32])

The secondary references fail to cure the deficiencies of Palma and Ting. Barlow does describe an optical measurement and a motion sensor (e.g., an accelerometer). But the optical measurement is only used to determine heart rate and not blood pressure. None of the above-mentioned analysis techniques for determining blood pressure are therefore described.

The Examiner cites Goodman, a reference that describes several optical techniques for measuring blood pressure, against dependent claim 8 and independent

claim 19. In response, we have cancelled claim 8 and amended independent claim 19 to include a light source and light detector that measure a time-dependent waveform, which is then analyzed to determine blood pressure. We disagree, however, with the Examiner's opinion that 'it would have been obvious to one of ordinary skill in the art at the time of the invention to use the device of Goodman in place of the blood pressure cuff of Palma, as modified, as it would merely be the substitution of one known means for measuring blood pressure for another' (Office Action, page 7). There is nothing in Palma that suggests using an optical technique for measuring blood pressure, just as there is nothing in Goodman that suggests using a motion sensor to detect an optimal measurement opportunity when a user is at rest. The references can only be combined with improper hindsight reconstruction. Moreover, unlike the claimed invention, Palma's 'movement classifier' is not meant to determine when the user's arm is at rest. As its name suggest, the sensor detects motion which an algorithm then classifies as 'calm, normal, and restless' (see, e.g., col. 5, line 52 – col. 6, line 4). The patent goes no further in describing the use of this information, and thus fails to describe our claimed steps of 'analyz[ing] the motion information from the motion sensor to distinguish between time-dependent waveforms (or any other type of data) generated while the user is moving and while the user is at rest' and 'calculat[ing] a blood pressure value from the time-dependent waveform generated when the user is at rest'. Thus even if combined with Goodman, which we assert can only be done in hindsight, the references still fail to describe all the limitations of our independent claims.

To reject independent claim 12 the Examiner combines Freund with Ting. But Freund describes a cuff-based system (1) that includes an inclination sensor (5) that measures the degree of inclination and motion of a patient's wrist to enhance a conventional blood pressure measurement. Thus these two references, even if combined, fail to teach the basic premises of our invention: 1) an optical measurement for determining blood pressure using a time-dependent waveform; 2) a motion sensor that determines when the patient is at rest, thereby indicating when to optically measure the time-dependent waveform; and 3) a microprocessor that calculates a blood pressure value from the time-dependent waveform generated when the user is at rest. While Freund does describe a motion sensor that can determine when a patient is at rest, the patent fails

to describe a microprocessor that determines this state and then proceeds to distinguish information (e.g. time-dependent waveforms) based on this criteria. Perhaps more importantly, the patent says nothing about specifically using information generated at rest in a blood pressure calculation. Our claims, as described above, include these limitations.

Swedlow, the Examiner's secondary reference combined with Freund and Ting, only describes pulse oximetry and not blood pressure. It therefore fails to cure any deficiencies of the primary references.

Finally, our new independent claims, 25 and 26, describe more specific methods for calculating blood pressure (i.e., derivatizing and fitting the time-dependent waveform). These claims are thus even further removed from the cited references.

In summary, we submit that the Examiner's references, even if combined, fail to teach all the limitations of the independent claims. The dependent claims are even further removed. We therefore respectfully ask the Examiner to issue a Notice of Allowance for this Application.

Respectfully Submitted,



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